K093223

5. 510(k) Summary

JAN 15 2010

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Limited summary for the GRAEL SYSTEM.

SUBMITTER'S NAME:	Compumedics Limited
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CONTACT PERSON:	Gordon Ferguson
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DATE OF SUBMISSION:	6 October 2009

Identification of device

Proprietary Name:	Compumedics Grael System
Common Name:	GRAEL SYSTEM
Classification Status:	Class II per regulations 882.1400, 868.2375
Product Codes:	GWQ, MNR

Predicate devices

Compumedics Limited believes the GRAEL SYSTEM is substantially equivalent to:

Device name:	Compumedics Siesta System
Supplier:	Compumedics Limited
510(k) number:	K003175

Other predicate devices have been used for comparison where features or technology in the Grael are not present in the Compumedics Siesta System. Other predicate devices compared are:

- Compumedics Summit IP, 510(k) number K040194
- Compumedics Somté PSG, 510(k) number K072201
- Compumedics E-Series System, 510(k) No.: K000068
- Compumedics P-Series System, 510(k) No.: K955841
- Neuroscan Labs Scan LT40, 510(k) No.: K001564
- Compumedics Neuvo System, 510(k) No.: K081151

Description of the System

Two different Grael models are available:

- ***Grael***, is a full channel device suitable for conducting either - PSG (polysomnographic - sleep), or EEG (electroencephalographic - neurological) studies;
- ***Grael EEG***, is a reduced channel device suitable for EEG studies only.

NOTE - Unless otherwise noted the information in this submission applies to both devices and the name Grael is used to refer to either device type. Where necessary the name Grael EEG is used to explicitly indicate functionality that is either not present in or unique to the Grael EEG.
NOTE - "Grail" is the project name that was assigned to the Grael hardware development project.

Grael and ***Grael EEG*** are standalone units, which together with sensors and a PC running Compumedics PSG Online and Profusion PSG software for sleep studies and/or Profusion EEG for EEG studies, can record, review and analyze a number of physiological parameters, including EEG, EOG, ECG and respiratory signals. These are then used as an aid in the diagnosis of respiratory and/or neurological related sleep disorders or other neurological conditions by qualified physicians. The system is comprised of *hardware* and *software* which, depending on the model type, provides up to 60 separate parameters for recording, review and analysis.

Power is supplied to the Grael via the network cable using either a Power over Ethernet (PoE) switch or power injector.

Intended use

The GRAEL SYSTEM is intended for use in the recording, displaying, analysis, printing and storage of human biological parameters such as heart and muscle activity, eye movement, breathing and body movements to assist in the diagnosis of various sleep disorders or neurological disorders. The Grael is designed for use in a hospital or other clinical environment. The Grael is only to be used under the direction of a physician.

Shared Technologies

The Grael System incorporates technology shared with other approved devices:

- Pulse Oximetry – Vampire module as used in Somté PSG (K072201)
- Inductive plethysmography – Technology as used in Summit IP (K040194)
- High frequency channels (EEG, EMG, and EOG) are identical to the technology used in the Siesta system (K003175), with the exception that these are sampled at a higher rate than the Siesta.
- Recording of the ECG channel is identical to the Somté PSG (K072201)
- Pressure monitoring is identical to the Somté PSG (K072201)

- Airflow monitoring via thermal oro-nasal sensor is identical to the Somté PSG (K072201)
- Automatic analysis via the Profusion PSG software is identical to the Somté PSG System (K072201)
- Profusion EEG (4.0) software is identical to that in the Neuvo System (K081151)
- Photic Stimulator – Identical to that included with the Scan LT40 (K001564)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Stuart King
Product Manager
Compumedics Limited
30-40 Flockhart Street
Abbotsford Vic 3067
Australia

JAN 15 2010

Re: K093223
Trade/Device Name: Compumedics GRAEL SYSTEM (Models: Grael and Grael EEG)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ, OLV, and OLZ
Dated: December 10, 2009
Received: December 11, 2009

Dear Mr. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K093223

Device Name: GRAEL SYSTEM

Indications for Use:

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Prescription Use ✓ OR Over the Counter Use_____
(Per Part 21 CFR 801 Subpart D)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kristen Bowsher
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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